

**Environmental Assessment for Marketing Order for a New
Smokeless Tobacco Product Manufactured by U.S. Smokeless
Tobacco Company LLC**

**Prepared by Center for Tobacco Products
U.S. Food and Drug Administration**

January 2, 2020

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1. Applicant and Manufacturer Information

Applicant Name	Altria Client Services LLC
Applicant Address	2325 Bells Road Richmond, VA 23234
Manufacturer Name	U.S. Smokeless Tobacco Company LLC
Product Manufacturing Address	800 Harrison Street Nashville, TN 37203 2303 Bells Road Richmond, VA 23234

2. Product Information

New Product	STN	Predicate Product
Copenhagen Long Cut	SE0015556	Copenhagen Long Cut

Product Category	Smokeless
Product Subcategory	Loose moist snuff
Product Packages	34.02 grams per can; fiberboard can with metal lid, paper side label, polyethylene shrink film and corrugated board shipping case

3. The Need for the Proposed Action

The proposed action, requested by the applicant, is for the Food and Drug Administration (FDA) to issue a marketing order under the provisions of sections 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act. The applicant wishes to introduce the new tobacco product into interstate commerce for commercial distribution in the United States.

The Agency shall issue marketing order if, after considering the substantial equivalence report submitted by the applicant, the new product is found substantially equivalent to the predicate product. The predicate product (SE0015104), which is not currently marketed, was previously found by FDA to be substantially equivalent and received a marketing order on May 22, 2019.

The new product differs from the predicate product in moisture content, tobacco cut size, tobacco type, and ingredients added (Confidential Appendix 1).

The applicant provided first- and fifth-year market volume projections for the new product (Confidential Appendix 2).

4. Alternative to the Proposed Action

The no-action alternative is the Agency does not issue a marketing order for the new tobacco product in the United States.

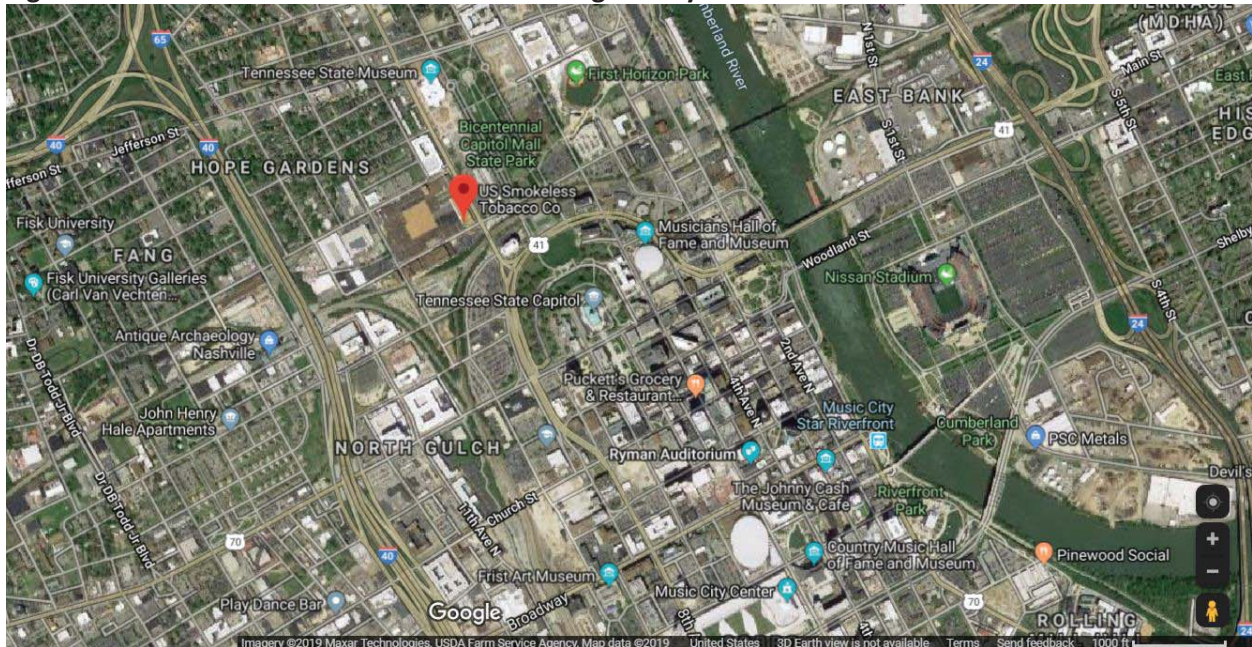
5. Potential Environmental Impacts of the Proposed Action and Alternatives - Manufacturing the New Product

The Agency evaluated potential environmental impacts that may be caused by manufacturing the new product and found no significant impacts.

5.1 Affected Environment

The new product would be manufactured at U.S. Smokeless Tobacco Company LLC, 800 Harrison Street, Nashville, TN 37203 (Figure 1) and 2303 Bells Road, Richmond, VA 23234 (Figure 2). The Nashville, TN facility is within an industrial park in downtown Nashville, with a railroad spur along its southern perimeter, offices and parking lots to the north, a six-lane highway to the west, a residential neighborhood to the north, and Cumberland River to the east.¹

Figure 1. Location of the Nashville Manufacturing Facility

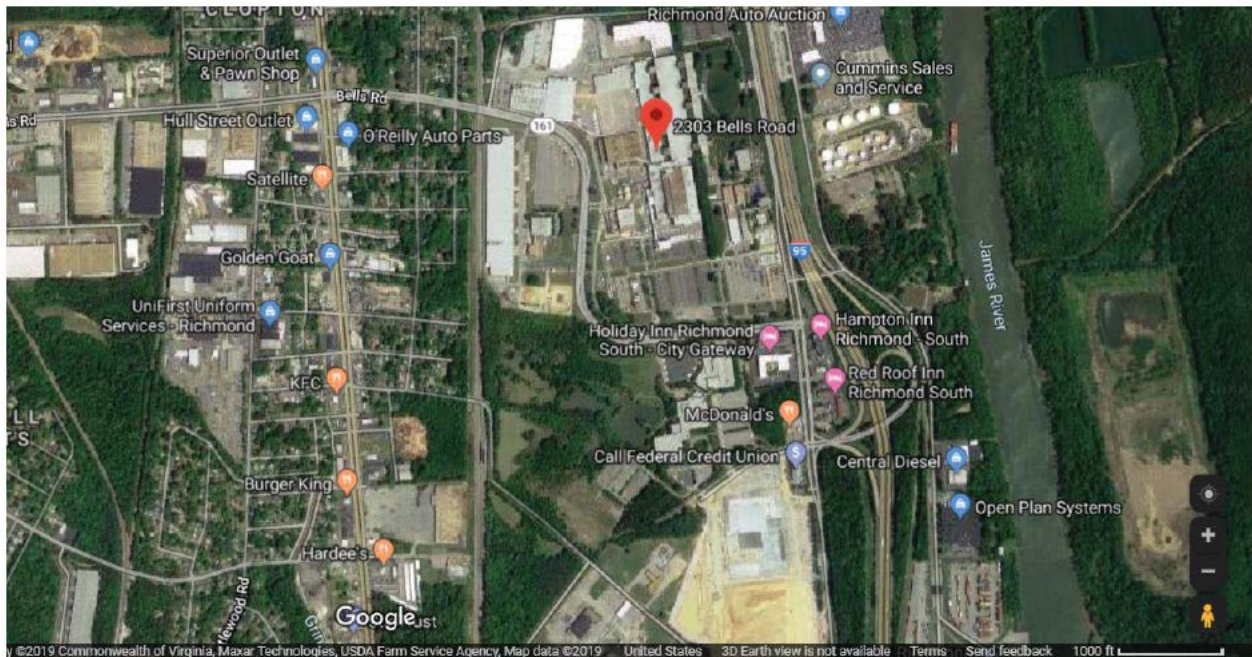


The Richmond, VA manufacturing facility is surrounded by a residential development across a road to the north; a two-lane divided road and an interstate freeway (I-95) to the east; two hotels, a fast food restaurant, and a gas station at the southeast corner; undeveloped forested land and a petroleum product pumping station and delivery terminal to the south; and a railroad to the west with a spur into the manufacturing facility.²

Figure 2. Location of the Richmond Manufacturing Facility

¹ Google. 2019. Map of 800 Harrison Street, Nashville, TN 37203. Retrieved from Google Maps: www.google.com/maps. December 3, 2019.

² Google. 2019. Map of 2303 Bells Road, Richmond, VA 23234. Retrieved from Google Maps: www.google.com/maps. December 3, 2019.



5.2 Analysis of Potential Environmental Impacts

The Agency evaluated the proposed action for potential environmental impacts from manufacturing the new product based on information gathered by the Agency and the applicant's submitted information.

Environmental Resource	Analysis of Potential Impacts
Air quality	The applicant stated that manufacturing the new product is not expected to result in changes in the types of air emissions from the manufacturing facilities and would not require new or revised permits.
Water resources	The applicant stated that manufacturing the new product is not expected to result in changes in the types of water discharges from the manufacturing facilities and would not require new or revised permits.
Land use and zoning	The applicant stated that there would be no facility expansion due to manufacturing the new product. Therefore, no changes in land use or zoning would occur as a direct impact from the proposed action.
Biological resources	The applicant stated that there would be no facility expansion due to manufacturing the new product and that manufacturing the new product would not result in changes in types of air emissions or water discharges. Therefore, no effects to biological resources would occur as a direct impact from manufacturing the new product.
Soils	The applicant stated that there would be no facility expansion due to manufacturing the new product. Therefore, no effects on soils would occur as a direct impact from manufacturing the new product.
Socioeconomic conditions	The applicant stated that there would be no facility expansion or changes in types of air emissions or water discharges at the facilities. Therefore, no socioeconomic effects (beneficial or adverse) would occur as a direct impact from manufacturing the new product.

Environmental Resource	Analysis of Potential Impacts
Solid waste and hazardous materials	The applicant stated that manufacturing the new product is not expected to result in emissions of new or additional compounds from the manufacturing facilities. Additionally, the applicant stated that no material changes in solid waste generation are expected to result from manufacturing the new product. Therefore, the Agency does not anticipate that manufacturing the new product would lead to the presence of new chemicals in the manufacturing waste stream.
Floodplains, wetlands, and coastal zones	The applicant stated that there would be no facility expansion due to manufacturing the new product. Therefore, no effects to floodplains, wetlands, or coastal zones would occur as a direct impact of manufacturing the new product.
Environmental justice	Because no significant environmental impacts were identified, there would be no disproportionate impacts to environmental justice populations that live near the manufacturing facilities.
Regulatory compliance	The applicant also stated that their manufacturing facilities are in compliance with all relevant federal, state, and local environmental regulations. The Agency's search for the manufacturing facilities in the U.S. Environmental Protection Agency's Enforcement and Compliance History Online (ECHO) database did not reveal any violations of environmental laws and regulations.

5.3 Cumulative Impacts

The Agency does not anticipate the proposed action to incrementally increase or change the chemicals released to the environment from the facilities' tobacco manufacturing. A search in the EPA's Toxic Release Inventory (TRI) database showed that in 2018, the U.S. Smokeless Tobacco's manufacturing facility in Nashville, Tennessee no ammonia and 231 pounds of nicotine and nicotine salts to air (Table 1).³ No other hazardous air pollutants were reported. The Richmond facility was not found in the ECHO database under the address provided, however, the Philip Morris USA facility occupies the same space but has a different address, 3601 Commerce Road, Richmond, VA 23234. Philip Morris and USSTC are corporate entities under the parent company, Altria. A search in the EPA's TRI database showed that in 2018, the Philip Morris USA manufacturing facility in Richmond, Virginia released no ammonia and 10,313 pounds of nicotine and nicotine salts to air, but released no other hazardous air pollutants at reportable levels (Table 2).⁴ Ammonia adversely affects ocular and respiratory systems; nicotine and nicotine salts have known adverse developmental effects.⁵ The TRI database search did not show that the U.S. Smokeless Tobacco manufacturing facilities disposed of, treated, or released into the environment any other toxicants associated with manufacturing tobacco products. In addition, EPA's ECHO database did not show that the facilities released the following reportable criteria pollutants: ozone, lead, particulate matter, or sulfur dioxide, at or above the reportable threshold levels to air.

³ U.S. Environmental Protection Agency (EPA). TRI Available at: https://www3.epa.gov/enviro/facts/tri/form_ra_download.html. Searched December 20, 2018.

⁴ U.S. Environmental Protection Agency (EPA). TRI Data Form R & A Download. Available at: https://www3.epa.gov/enviro/facts/tri/form_ra_download.html. Searched on July 18, 2019.

⁵ Chemical health effects information comes from the ●SHA Carcinogen List and the TRI-CHIP datasets.

Table 1. Management of Chemical Waste Associated with Manufacturing Tobacco Products at Nashville U.S. Smokeless Tobacco Facility in 2018

Production-Related Waste Managed or Released			Chemical Mass (Pounds)
Recycled			18,345
Energy Recovery			0
Treated			671
<i>Subtotal Waste Managed</i>			<i>19,016</i>
On-Site Release	Air	Ammonia	0
		Nicotine and Salts	231
	Water	Ammonia	0
		Nicotine and Salts	0
	Land	Ammonia	0
		Nicotine and Salts	0
Off-Site Disposal/Release			32,382
<i>Subtotal Waste Released</i>			<i>32,613</i>
Total Production-Related Waste			51,398

Table 2 Management of Chemical Waste Associated with Manufacturing Tobacco Products at Richmond Philip Morris USA Facility in 2018

Production-Related Waste Managed or Released			Chemical Mass (Pounds)
Recycled			122,530
Energy Recovery			0
Treated			94,266
<i>Subtotal Waste Managed</i>			<i>216,796</i>
On-site Release	Air	Ammonia	0
		Nicotine and Salts	10,313
	Water	Ammonia	0
		Nicotine and Salts	0
	Land	Ammonia	0
		Nicotine and Salts	0
Off-site Release			35,528
<i>Subtotal Waste Released</i>			<i>45,841</i>
Total Production-Related Waste			262,637

5.4 Impacts from No-Action Alternative

The environmental impacts of the no-action alternative would not change the existing conditions of manufacturing smokeless tobacco products, as many similar tobacco products would continue to be manufactured at the listed facilities.

6. Potential Environmental Impacts of the Proposed Action and Alternatives - Use of the New Product

The Agency evaluated potential environmental impacts that may be caused by use of the new product and found no significant impacts.

6.1 Affected Environment

The affected environment is the entire United States because the marketing order would allow for the new tobacco product to be sold to consumers nationwide.

6.2 Analysis of Potential Environmental Impacts

The Agency evaluated the proposed action for potential environmental impacts from use of the new product based on Agency-gathered information and the applicant’s submitted information.

Environmental Resource	Analysis of Potential Impacts
Environmental justice	The new product is likely to be used by the same consumers that use existing smokeless tobacco products, competing for the same market share. Therefore, no change in impacts to environmental justice populations is expected.

6.3 Cumulative Impacts

The Agency did not identify any actions that, when considered with the new products’ use under the proposed action, would lead to cumulative impacts.

6.4 Impacts from No-Action Alternative

The no-action alternative would not change the existing use of other smokeless tobacco products in the United States, as many similar smokeless tobacco products would continue to be marketed and therefore used.

7. Potential Environmental Impacts of the Proposed Action and Alternatives - Disposal of the New Product

The Agency evaluated potential environmental impacts that may be caused by disposal of the new product and found no significant impacts.

7.1 Affected Environment

The affected environment is the entire United States because the marketing order would allow the new tobacco product to be sold to consumers nationwide who would dispose of the used new product and packaging as municipal solid waste, recycled material, or litter.

7.2 Analysis of Potential Environmental Impacts

The proposed action was evaluated for potential environmental impacts from disposal based on Agency-gathered information and the applicant's submitted information.

Environmental Resource	Analysis of Potential Impacts
Biological resources	Proper disposal of the used new product and packaging in the municipal solid waste stream would not affect biological resources. Improper disposal (littering) of the used new product could lead to terrestrial wildlife having direct exposure to the used product and hazardous substances leaching to aquatic environments and soil. However, no net increase in littering is expected because the new product would compete for the same market share occupied by currently marketed smokeless tobacco products; therefore, these impacts are not considered significant.
Environmental justice	Because no significant environmental impacts were identified, there would be no disproportionate impacts to environmental justice populations from disposal of the used new product and packaging waste.
Water resources	Proper disposal of the used new product and packaging in the municipal solid waste stream would not affect water resources. Improper disposal (littering) of the used new product could result in hazardous substances leaching to water systems. However, no net increase in littering is expected because the new product would compete for the same market share occupied by currently marketed smokeless tobacco products; therefore, these impacts are not considered significant.
Solid Waste	The distribution of waste generated due to disposal of the new product and packaging is expected to correspond to the pattern of product use in the United States. However, no net increase in solid waste is expected because the new product would compete for the same market share occupied by currently marketed smokeless tobacco products; therefore, these impacts are not considered significant.
Regulatory compliance	The new product has no features that would lead to a different rate of used product littering compared to currently marketed smokeless tobacco products. Despite state and local ordinances, it is assumed that noncompliance (littering) would occur at the same rate for the new product as for currently marketed smokeless tobacco products; therefore, these impacts are not considered significant.

7.3 Cumulative Impacts

The Agency did not identify any action that, when considered with the new products' disposal under the proposed action, would lead to cumulative impacts.

7.4 Impacts from No-Action Alternative

The no-action alternative would not change the existing disposal of other smokeless tobacco products in the United States, as many similar smokeless tobacco products would continue to be marketed and therefore disposed of.

8. List of Preparers

The following individuals were primarily responsible for preparing and reviewing this programmatic environmental assessment:

Preparer:

Dilip Venugopal, Ph.D., Center for Tobacco Products

Education: M.S. in Ecology and Ph.D. in Entomology

Experience: Seventeen years in various scientific activities

Expertise: NEPA analysis, environmental impact analysis and risk assessment, applied ecology, geo-statistics

Reviewer:

Hoshing W. Chang, Ph.D., Center for Tobacco Products

Education: M.S. in Environmental Science and Ph.D. in Biochemistry

Experience: Eleven years in FDA-related NEPA review

Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

9. List of Agencies and Persons Consulted

Not applicable.

Confidential Appendix 1: Comparison of the New Product to the Predicate Product

SE Report	Characteristic	Change
SE0015556	Tobacco moisture content	The new product has an increased moisture content.
	Tobacco types	The new product contains addition of (b) (4) and a reduction in all other tobacco types
	Ingredients	The new product has additional ingredients not included in the predicate product, these include (b) (4) and (b) (4). The new product contains equal or lower levels of all other ingredients added to tobacco that are present in the predicate product.

Confidential Appendix 2: First- and Fifth-Year Market Volume Projections for New Product

STN	Unit	Market Volume	
		First-Year Projection	Fifth-Year Projection
SE0015556	Can	(b) (4)	
	Metric Tons		

The applicant stated that the predicate product is not currently on the market.